K010708

APR 3 0 2001

510(k) SUMMARY

SUBMITTED BY

Lynn Rodarti
Manager, Regulatory and Clinical Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

(949) 453-3200

March 7, 2001

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR §807.92.

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Piston Syringe
Common/Usual Name: Piston Syringe
Product Classification: Class II
Proprietary Name: Applicator Tip/Dual Sprayer Kit

PREDICATE DEVICE

The predicate device is the Harvest Technologies Dual Liquid Applicator.

INDICATIONS-FOR-USE

The Applicator Tip/Dual Sprayer Kit is indicated for simultaneous delivery of two non-homogeneous liquids to the same area.

DEVICE DESCRIPTION

The Applicator Tip/Dual Sprayer Kit consists of an Applicator Tip or Dual Sprayer, Syringe Holder, Syringe Clip, and two BD Syringes. Syringes attached to the Luer ports of the Applicator Tip or Dual Sprayer can express their solutions through the Applicator Tip or Dual Sprayer body, with mixing occurring as the solutions exit the opening in the Applicator Tip or Dual Sprayer.

COMPARISON TO THE PREDICATE DEVICE

The Applicator Tip/Dual Sprayer Kit is substantially equivalent to the Harvest Technologies Dual Liquid Applicator. Both devices are intended to simultaneously deliver two non-homogenous liquids to the same area. Both devices also contain the same basic components. Based on this information, Interpore Cross International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to the existing legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2001

Ms. Lynn M. Rodarti
Manager of Regulatory and Clinical Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402

Re: K010708
Trade/Device Name: Applicator Tip/Dual Sprayer Kit
Regulation Number: 880.5860
Regulatory Class: II
Product Code: FMF
Dated: March 7, 2001
Received: March 9, 2001

Dear Ms. Rodarti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010708

Device Name: **Applicator Tip/Dual Sprayer Kit**

Indications-For-Use:

The Applicator Tip/Dual Sprayer Kit is indicated for simultaneous delivery of two non-homogeneous liquids to the same area.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010708